REMARKS/ARGUMENTS

Claims 1-20 are pending in the above-referenced application.

Claim 1 has been amended to correct a typographical error and claims 12-20 added to further define Applicant's invention, all of which being dependent claims.

This is a Response to the Office Action dated May 29, 2007 wherein the Examiner rejected: (1) claims 1, 3, 4, 5-11 under §103(a) as being unpatentable over Woehr et al (USPN 6,117,108) in view of Rogers et al. (USPN 5,405,323); and (2) claims 1 and 2 under §103(a) as being unpatentable over Woehr et al (USPN 6,287,278 B1) in view of Rogers et al. (USPN 5,405,323)

In view of the following remarks, reconsideration and a notice of allowance are respectfully requested.

§103(a) Rejection by Woehr et al. ('108) in view of Rogers et al. ('323)

In rejecting claims 1, 3, 4, 5-11 the Examiner contends that Woehr ('108) discloses all the elements and limitations disclosed in claim 1, except for "a check valve disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after removal of the needle". The Examiner relied on Rogers ('323) to disclose "a check valve 10 disposed between the catheter tube 16 and the needle guard element (26 and 33) in the catheter hub (13) through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (figures 1 and 2 and Col. 3, lines 30-55 and Col. 4, lines 23-62). The Examiner concluded that "since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle".

Preliminarily, Applicant reminds the Examiner that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or

motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP 706.02(j).

Independent claim 1 recites a catheter insertion device comprising a hollow-cylindrical catheter hub having a catheter tube attached a distal end thereof, a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position, a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub, wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (emphasis added)

Independent claim 10 recites a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve (emphasis added).

Independent claim 11 recites a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube and comprising an engaging section near a needle tip; a valve for regulating fluid flow positioned inside the interior cavity of

the catheter hub, said valve comprising an opening and the needle projecting through the opening; and a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub (emphasis added).

Thus all three independent claims disclose a check valve for regulating fluid flow.

In contrast, the '108 Woehr patent discloses a safety IV catheter, in which the needle tip is automatically covered after needle withdrawal to prevent the health-care worker from making accidental contact with the needle tip. The safety IV catheter disclosed by Woehr, as shown in Figs. 1A and 1B and described in column 4, lines 43-49, includes a needle hub 12, a catheter hub 26, a needle 16, a protective needle guard 40. When the needle 16 is withdrawn from the patient, the protective needle guard 40 which is located within the hub chamber 36 automatically snaps into a retracted position wherein it prevents the needle tip from further movement. Nowhere in the Woehr reference is disclosed a check valve assembly between the catheter and the needle guard element to prevent outflow of the blood upon removal of the needle. .

The '323 Rogers patent is. relied on to disclose a check valve assembly. Rogers describes a catheter check valve assembly 10 which includes a body member 11, a separator 12, a separator body 13, a duckbill valve 14 and an end cap 15 in which is mounted a catheter 16. The separator body incorporates a finger tab 44, called a "head", for moving the separator from between an IV infusion position FIG. 3 (See also Col. 4:40-49) and a blood sampling position FIG. 4 (See also Col. 4:56-62). As described in the '323 patent specification, when the assembly 10 is in the blood sampling mode, a user "move[s] the separator 12 and separator body 13 to the forward position shown in FIG. 4, thus opening duckbill valve 14 and permitting blood sample to be removed through the passageway 27."

In short, for the valve assembly 14 of the '323 patent to operate, the tubular portion 12A of the separator must project through both the annular seal 26 and the slit 48 (FIGs. 4 and 9) to provide a fluid pathway between the catheter tube 16 and the cavity at the luer lock fitting 46 (FIG. 3) of the body member 11.

Thus, to use the check valve assembly disclosed by the '323 Rogers patent with the catheter device disclosed by the '108 Woehr patent would require significant changes in the

arrangement of various elements and would impact the functionality of the needle guard element if the changes proposed by the Examiner were made. For example, the hub of the Woehr catheter device would need to be modified to accept the valve assembly taught by Rogers while at the same time accommodates the guard at a proximal position thereof. Furthermore, a separator 12 and separator body would project over the needle and the needle guard disclosed by the Woehr reference would be positioned over the tubular portion 12A of the separator in the Examiner's proposed modification. However, doing so would first require widening or expanding the diameter of the opening of the wall of the clip, which would make the opening larger than the crimp on the needle and therefore will not engage the needle in the protective position.

Still furthermore, because the clip disclosed by Woehr will be positioned over the tubular portion 12A disclosed by Rogers, the clip will never engage the needle, or vice versa. In other words, the tubular portion 12A disclosed by Rogers would act as a divider or wall and never allow the needle guard to engage the crimp on the needle to cover the needle tip. Accordingly, the proposed modification is defective and will not operate. Thus, the two references can not be combined to reject the claimed device without undue modification.

In view of the foregoing remark, Applicant submits that the combination of Woehr and Rogers as disclosed fails to teach or suggest all the limitations of the independent claims 1, 10 and 11 as required by MPEP 706.02(j). Thus, rescission of the §103(a) rejection of the foregoing claims is respectfully requested. Since claims 2-9 depend from claim 1, they too are allowable for at least the same reasons and allowance is respectfully solicited.

§103(a) Rejection by Woehr et al. ('278) in view of Rogers et al. ('323)

In rejecting claims 1 and 2, the Examiner contends that Woehr ('278) discloses all the elements and limitations of claim 1 except for "a check valve held between a distal hub element and a proximal hub element which are joined to one another". The Examiner relies on Rogers ('323) to disclose "a check valve (10) held between a distal hub element (55) and a proximal hub element (53) which are joined to one another (figure 2)) . The Examiner contends that a person

of ordinary skill in the art can readily modify Woehr's catheter insertion device to include a check valve taught by Rogers to render the claims obvious.

The '278 Woehr patent is a continuation-in-part of the '108 Woehr patent, and thus contains similar disclosures with the addition of alternatives embodiments for the operating mechanism of the needle guard. Similar to the '108 Woehr reference, nowhere in the '278 Woehr patent is disclosed or suggested a check valve "wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle", as recited by claim 1.

Rogers ('323) is relied on to disclose a check valve (10) held between a distal hub element (55) and a proximal hub element (53) which are joined to one another. As set forth above, implementation of the check valve taught by Rogers ('323) into the catheter insertion device as described by Woehr ('108) or ('278) would negate the functionality of the needle guard element in the catheter. More specifically, because the needle guard will never engage with the needle crimp due to the tubular portion 12A of the separator 12 disclosed by Rogers, the proposed combination is defective. Therefore, the combination of Woehr ('108) or ('278) with Rogers ('323) is defective and fails to render claim 1 obvious. In view of the foregoing, Applicant respectfully requests rescission of the §103(a) rejection and allowance of claim 1. Since claim 2 depends from claim 1, it too is allowable for at least the same reasons.

In view of the foregoing remarks, the Application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner find it necessary to speak with Applicant's attorney; he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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